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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/924,338	08/07/2001	James Tobin	22058-516-DIV-CON	3551

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EXAMINER

MERTZ, PREMA MARIA

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 11/29/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/924,338

Applicant(s)
James Tobin

Examiner
Prema Mertz

Art Unit
1646



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 25, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-37 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-12, 29-34, drawn to an isolated polynucleotide, a host cell transformed with the polynucleotide, and a process for producing a human IL-11 receptor (IL-11R) protein, classified in Class 435, subclass 69.1.

Group II. Claims 13-17, and 35-37, drawn to an isolated human IL-11R protein, classified in Class 530, subclass 350.

Group III. Claim 18, drawn to an antibody against human IL-11R, classified in Class 530, subclass 387.1.

Group IV. Claims 19-20, drawn to a method of identifying an inhibitor of IL-11 binding to the human IL-11 receptor, classified in Class 435, subclass 7.1.

Group V. Claims 21-22, drawn to an inhibitor of IL-11 binding to the human IL-11 receptor and a pharmaceutical composition thereto, Class and subclass undeterminable.

Group VI. Claims 23 and 26, drawn to a method of inhibiting binding of IL-11 to the IL-11 receptor by administering an inhibitor, Class and subclass undeterminable.

Group VII. Claims 24 and 27, drawn to a method of inhibiting binding of IL-11 to the IL-11 receptor by administering an IL-11R, classified in Class 514, subclass 2.

Group VIII. Claim 25 and 28, drawn to a method of inhibiting binding of IL-11 to the IL-11 receptor by administering an antibody, classified in Class 424, subclass 145.1.

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The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)). In the instant case the protein can be prepared by the process of Group I as shown above. Alternatively, the protein can be prepared by materially different processes, such as by chemical synthesis, or obtained from nature using various isolation and purification protocols.

The Inventions I-III and V are independent and distinct, each from the other because the polynucleotide, host cell transformed with the polynucleotide, and a process for producing a human IL-11R protein of Group I, the IL-11R protein of Group II, the antibody of Group III and the inhibitor of Group VI, do not require each other for their practice; have separate uses, such as diagnostic probes for DNA hybridization or serving as a selectable marker (by use of Group I) versus the generation of specific antibodies (by use of Group II) versus the screening of expression libraries (by the use of Group III) versus to study the mechanism of IL-11 signal transduction or used therapeutically (by the use of Group VI); and each of the products are physically, chemically and biologically distinct from each other, and if patentable would be patentably distinct.

Inventions II and IV, VII are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as

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claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the protein can be used to treat a disorder as shown by the method of Group VII or to identify an inhibitor as shown by the method of Group IV. Alternatively, the protein can be used to make antibodies or it could be used in diagnostic procedures.

Inventions III and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the antibody can be used to treat a disorder as shown by the method of Group VIII. Alternatively, the antibody could be used to purify the protein by immunoaffinity procedures or could be used to screen expression libraries or could be used in diagnostic procedures.

Inventions V and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the inhibitor can be used to treat a disorder as shown by the method of Group VI. Alternatively, the inhibitor could be used to study the mechanism of IL-11 signal transduction or could be used in diagnostic procedures.

The methods of Groups IV and VI-VIII are independent and distinct because they have different goals, method steps, starting materials, and are not required one for the other. In addition,

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the search for one of the methods would not be expected to reveal all references relevant to the other, and therefore the search and examination would be unduly burdensome.

Inventions I and IV, VI-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP. § 806.04, MPEP. § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions II and VI, VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP. § 806.04, MPEP. § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions III and IV, VI-VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP. § 806.04, MPEP. § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions V and IV, VII-VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP. § 806.04, MPEP. § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject

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matter as defined by MPEP. § 808.02, the Examiner has *prima facie* shown a serious burden of search (see MPEP. § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (703) 308-4229. The examiner can normally be reached on Monday-Friday from 8:00AM to 4:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Prema Mertz
Prema Mertz Ph.D.
Primary Examiner
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November 22, 2002